

REMARKS/ARGUMENTS

The rejections presented in the Office Action dated March 15, 2007 (hereinafter Office Action) have been considered. Claims 1-12, 14, and 35-56 remain pending in the application. Reconsideration of the pending claims and allowance of the application in view of the present response is respectfully requested.

Claim 1 has been amended with subject matter from now canceled claim 13. Accordingly, no new matter has been added. The Applicant respectfully submits that the present responsive amendment should be entered and considered, because the Examiner has previously searched and considered the features of claim 13 in the prior Office Action. Hence, the Applicant submits that the present responsive amendment does not necessitate a new search that would present an undue burden to the Examiner.

Claim 1 was amended to address the § 101 statutory subject matter rejection. The amendment to claim 1 was not necessitated by prior art. The Applicant respectfully asserts that the collection and storage of sleep quality data has clear, practical, and specific application providing utility that would be immediately apparent to one skilled in the art. Collection and storage of sleep quality data is not an intangible abstraction as asserted by the Examiner, at least for the reasons that 1) collection and storage of sleep quality data involves the alteration of an article, and 2) collection and storage of sleep quality data provides diagnostic and/or therapeutic functionality which would not be possible absent the stored data.

Claim 1 meets various tests for § 101 statutory subject matter articulated in the Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility, 1300 Off. Gaz. Pat. Office 142. A claim should be reviewed to determine if the claim “provides a transformation or reduction of an article to a different state or thing.” (See Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility, 1300 Off. Gaz. Pat. Office 142, page 19). “When functional descriptive material is recorded on some computer-readable medium, it becomes structurally and functionally interrelated to the medium and will be statutory in most cases since the use of technology permits the function of the descriptive material to be recognized.” (Id., at page 50)

With respect to claim 1, both of these tests are met. First, storage of data by a device involves altering the state of the device memory to retain the stored information. In addition, the stored sleep quality data permits therapeutic and/or diagnostic functionality to be utilized. Sleep quality assessments depend on acquiring sleep-related data, including the patient's typical sleep patterns and the physiological, environmental, contextual, emotional, and/or other conditions affecting the patient during sleep. (See the Applicant's disclosure at page 10, lines 9 – 11). Absent the collection and storage of sleep quality data, various diagnostic and/or therapeutic processes would not be implementable. Therefore, collection and storage of sleep quality data by an implantable device provides a practical and tangible utility.

For at least the reasons provided above, claims 1-12 and 14 are clearly in compliance with § 101.

Claims 1-3, 5, and 9-14 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,641,542 to *Cho et al.* (hereinafter "*Cho*") in view of U.S. Patent No. 5,245,995 to *Sullivan et al.* (hereinafter "*Sullivan*"). The Applicant notes that while claims 35-46 were not explicitly rejected by the combination of *Cho* and *Sullivan*, it appears that claims 35-46 were intended to be rejected by the combination. Accordingly, the Applicant will address the rejection as if claims 35-46 are rejected. The Applicant's discussion of claims 35-46 is only to be considered, for any purpose, only to the extent that it was intended that claims 35-46 be rejected by the combination of *Cho* and *Sullivan*.

Four factual inquiries are necessary for consideration and determination of obviousness under 35 U.S.C. 103:

- (A) Determining the scope and contents of the prior art;
- (B) Ascertaining the differences between the prior art and the claims in issue;
- (C) Resolving the level of ordinary skill in the pertinent art; and
- (D) Evaluating evidence of secondary considerations.

-*Graham v. John Deere*, 383 U.S. 1 (1966).

The Applicant's independent claims 1 and 35 each recite, among other features, some variation of detecting at least one physiological condition and at least one non-physiological condition associated with sleep quality of a patient, the non-physiological condition comprising an ambient condition external to the patient other than time that affects the sleep quality of the patient.

The Office Action states that "Cho et al. do not explicitly disclose measuring a non-physiological condition, other than time, comprising an ambient condition external to the patient that affects sleep quality, as recited in the claim. Sullivan et al. teach that it is known in the art to detect ambient conditions such as background noises, as part of a method of detecting sleep apnea (Col. 3; 3-130)." (Office Action, Page 3).

The cited portion of *Sullivan* briefly outlines International Patent Publication WO/86/05965. According to *Sullivan*, WO/86/05965 discloses detecting breathing sounds, comparing the breathings sounds with background noises, and further comparing the results of the breathing sounds/background noise comparison to a database to indicate whether the patient is undergoing a normal or abnormal breathing pattern. (Col. 3, Lines 3-13). The Applicant respectfully submits that *Sullivan* describes methods to gather and refine breathing sounds to characterize breathing patterns. As such, the cited portion of *Sullivan* discusses sensing physiologic conditions, but does not disclose detecting a non-physiologic condition associated with sleep quality.

Sullivan, and WO/86/05965, disclose sensing background sounds and comparing the background noise to a respiration signal to filter the background noise out of the respiration signal, resulting in a purer respiration signal for comparison to a respiration signal database. (See *Sullivan*, Col. 3, Lines 3-13; and WO/1986/05965, Page 6, Line 33 – Page 7, Line 9; Page 8, Lines 5-13; Page 12, Lines 4-23; and Page 24, Lines 1-16). Thus, *Sullivan* and WO/1986/05965 use the background noise to enhance detecting of a physiologic (breathing) parameter, and do not contemplate background noise as a non-physiological condition itself, nor detecting background noise as a non-physiological condition that affects the sleep quality of the patient. Moreover, the fact that *Sullivan* and WO/1986/05965 use sensed background noise to filter out background noise clearly demonstrates that *Sullivan* and

WO/1986/05965 are uninterested in collecting background noise and do not appreciate the significance of sounds as a non-physiological condition that affects sleep quality.

The Applicant respectfully submits that *Sullivan*'s mere mention of a "background sound sensor" and "background noises" does not constitute a teaching or suggestion of detecting at least one non-physiological condition associated with sleep quality of a patient, the non-physiological condition comprising an ambient condition external to the patient other than time that affects the sleep quality of the patient. As such, the combination of *Cho* and *Sullivan* does not teach each and every element and limitation of independent claims 1 and 35. Dependent claims 2, 3, 5, 7-12, 14, and 35-45 also appear to be rejected based on the combination of *Cho* and *Sullivan*. Each of claims 2, 3, 5, 7-12, 14, and 36-46 depend from one of independent claims 1 and 35, respectively. Independent claims 1 and 35 are not obvious for at least the reason that the cited references fail to teach or suggest each and every limitation recited in each claim. Furthermore, while the Applicant does not acquiesce to the particular rejections to these dependent claims, it is believed that these rejections are now moot in view of the remarks made in connection with independent claims 1 and 35. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited references. Moreover, if an independent claim is nonobvious under 35 U.S.C. §103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). The Applicant respectfully requests withdrawal of the §103(a) rejection of claims 1-3, 5, 7-12, 14, and 35-46 and notification that these claims are in condition for allowance.

Claim 6 stands rejected under 35 U.S.C. §103(a) as being unpatentable over *Cho* in view of *Sullivan*, as applied above, and further in view of U.S. Patent No. 5,146,918 to *Kallok et al.* (hereinafter "*Kallok*").

The Applicant reasserts the arguments presented above regarding the failure of *Cho* and *Sullivan* to teach or suggest each of the limitations of Applicant's claim 1, from which claim 6 depends. *Kallok* does not overcome the deficiencies of the *Cho/Sullivan* combination with regard to describing all the limitations of Applicants claim 1. Therefore

the references asserted in the rejection of claim 6 cannot support prima facie obviousness because the combination of elements does not meet the requirement that the references must teach or suggest all of the limitations of the claim. As such, the Applicant respectfully requests withdrawal of the §103(a) rejection of claim 6 and notification that this claim is in condition for allowance.

Claims 47-56 stand rejected under 35 U.S.C. §103(a) as being unpatentable over *Cho* in view of U.S. Patent No. 6,361,494 to *Lindenthaler* (hereinafter “*Lindenthaler*”).

The Applicant’s independent claim 47 recites, among other features, detecting one or more conditions associated with the sleep quality of a patient during a period of wakefulness; collecting sleep quality data based on the detected one or more conditions.

Cho discloses sleep data collection and sleep respiratory therapy delivery. (Abstract). *Lindenthaler* discloses diagnosing sleep apnea by use of data taken from an electrode placed in a patient’s mouth. (Col. 2, Lines 21-31).

The Applicant maintains and reiterates the previously stated remarks concerning the rejection of claim 47. Assuming *arguendo*, even if *Cho* and *Lindenthaler* are properly combinable in the way proposed in the Office Action, the combination does not teach all elements of at least the Applicant’s independent claim 47, as discussed below.

For example, *Cho*’s data collection process starts with detecting the onset of sleep 610 and stops if the patient wakes 650. (Col. 10, Line 52; see Fig. 6). *Cho* does not provide that the disclosed procedures are based on any conditions detected during a period of wakefulness. Moreover, once *Lindenthaler* diagnoses a patient as having a sleep apnea condition, *Lindenthaler* does not disclose collecting sleep quality data based on the detected sleep apnea condition. Therefore, even if *Lindenthaler*’s disclosure is construed as “detecting one or more conditions associated with the sleep quality of a patient during a period of wakefulness,” neither *Cho* nor *Lindenthaler* provide a teaching or suggestion of collecting sleep quality data based on the detected one or more conditions.

The Applicant respectfully submits that the first two elements of independent claim 47 have an interrelationship that cannot be accounted for simply by *Lindenthaler*’s

wakefulness sleep apnea detection and *Cho*'s nighttime data collection. No processes of *Cho* are based on any detection that occurs before sleep is detected and *Lindenthaler* does not disclose any data collection based on the sleep apnea condition diagnosis.

The Applicant's independent claim 47 recites, among other limitations, detecting one or more conditions associated with the sleep quality of a patient during a period of wakefulness; collecting sleep quality data based on the detected one or more conditions, which is clearly not taught nor suggested by *Cho*, even in combination with *Lindenthaler*. As such, the combination of *Cho* and *Lindenthaler* fails to teach or suggest each and every element and limitation of independent claim 47.

Each of dependent claims 48-51 respectively recite one of the one or more detected conditions that, according to independent claim 47, are detected during a period of wakefulness. In addressing each of claims 48-51, the Office Action identifies some portion of *Cho* that discloses a parameter. As discussed above, *Cho* does not disclose that these parameters are detected during a period of wakefulness. Rather, *Cho* teaches, according to the flow chart of Fig. 6, sensing and gathering sleep data once it has been detected that the patient is asleep 620 and stopping data collection if the patient wakes 650.

In specific regard to dependent claim 50, which states that "detecting the one or more conditions comprises detecting a nervous system condition", the Applicant points out that Page 7 of the Office Action states that "Cho et al., as modified by Sullivan et al., do not explicitly disclose detecting a nervous system condition." The Applicant respectfully submits that it is unclear why *Cho* in combination with *Sullivan* does not disclose a nervous system condition, but that *Cho* in combination of *Lindenthaler* does, particularly when the Office Action does not rely on *Lindenthaler* to disclose any nervous system aspects.

As such, *Cho* fails to provide a teaching or suggestion of detecting the subject matter of dependent claims 48-51 during a period of wakefulness. Additionally, *Lindenthaler* does not disclose these parameters. Therefore, the Applicant respectfully submits that the combination of *Cho* and *Lindenthaler* fails to teach or suggest each and every element and limitation of each of dependent claims 48-51.

For at least these reasons, as well as the reasons set forth in the Applicant's previous Office Action responses, the Applicant respectfully asserts that the combination of *Cho* and *Lindenthaler* as proposed in the Office Action do not support a case of *prima facie* obviousness with regard to claims 47-56, and that these claims are patentable over the asserted combination.

It is to be understood that the Applicant does not acquiesce to Examiner's characterization of the asserted art or the Applicant's claimed subject matter, nor of the Examiner's application of the asserted art or combinations thereof to the Applicant's claimed subject matter. Moreover, the Applicant does not acquiesce to the Examiner's statements or conclusions concerning what would have been obvious to one of ordinary skill in the art, obvious design choices, common knowledge at the time of Applicants' invention, officially noticed facts, and the like. The Applicant reserves the right to address in detail the Examiner's characterizations, conclusions, and rejections in future prosecution.

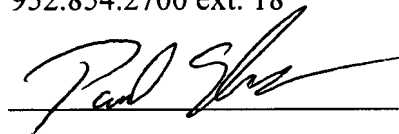
Authorization is given to charge Deposit Account No. 50-3581 (GUID.058PA) any necessary fees for this filing. If the Examiner believes it necessary or helpful, the Examiner is invited to contact the undersigned attorney to discuss any issues related to this case.

Respectfully submitted,

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